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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,277	05/29/2001	Lars Peter Klitnose	P200000067	5508

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PATENT DEPARTMENT
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
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NEW YORK, NY 10036

EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 01/14/2004

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/867,277

Applicant(s)

KLITMOSE, LARS PETER

Examiner

Anu Ramana

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Art Unit: 3732

DETAILED ACTION

Claim Objections

In claim 22, the “one or more further devices” (line 4) appears to be the same as the “further device” recited in claim 21. Appropriate correction is required.

Claim 29 is objected to due to the following informalities. In line 8, “the further” should be “the further devices.” Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite “main device” and “further device” while the specification discloses a “basis module” and “functional modules.” The cooperation of the main and further devices is not described.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 21-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 21, it is unclear whether the “at least two devices (lines 2-3),” are the “at least one main device” (line 5) and the “at least a further device” (line 7). Appropriate correction is required.

Art Unit: 3732

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

As best understood, in light of the 112 rejections, claims 21-24, 26-29 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Castellano et al. (US 5,593,390).

Regarding claims 21-24, 26-29 and 31-33, Castellano et al. disclose a hand-held medical apparatus including a main device (10,32) and further devices 28 and 204 wherein the main device has a housing 16 to hold a replaceable medication cartridge 22, the cartridge having a movable wall 84; a battery and power convertor or “means to supply electrical energy” 50; and an electronic means (42,44) for monitoring and controlling medication delivery and for communicating with a user; wherein device 204 is a blood glucose monitor (Figures 3, 5, 15, col. 7, lines 27-49, col. 8, lines 66-67, col. 9, lines 1-39, col. 10, lines 38-67, col. 11, lines 1-67, col. 14, lines 13-67 and col. 15, lines 1-40).

Regarding claims 31 and 32, with regard to the electronic means “adapted to receiveprocedures,” is not a positive limitation but only requires the ability to so perform and does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al. in view of Brown (US 4,741,736).

Art Unit: 3732

Castellano et al. do not disclose that medication cartridge 22 is connected to a replaceable catheter.

It is well known to use a catheter to transfer medication from a delivery device such as a syringe to a patient. For example, Brown teaches a drug delivery device 10 wherein the medication cartridge 20 is connected to a catheter 40 to deliver medication from a drug cartridge 20 to a patient (Figure 1 and col. 4, lines 32-50).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a catheter, as taught by Brown, for the purpose of transferring medication from cartridge 22 of the device of the combination of Castellano et al. and Brown to a patient.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al. in view of Kovelman (US 6,110,152).

Castellano et al. do not disclose that an item of information can be placed on medication cartridge 22 or a means for reading the item of information placed on the medication cartridge.

Kovelman teach an information providing means 5 coupled to a medication cartridge 3 wherein the information providing means, for example a bar code disposed on an exterior surface of the medication cartridge, is further operatively coupled to an electronic delivery device 1 to control electronic delivery device 1 and to improve the performance of the electronic delivery device 1 (Figure 6, col. 1, lines 27-38 and lines 63-67, col. 2, lines 1-3 and lines 11-15 and col. 3, lines 1-6 and lines 49-54).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an information providing means, as taught by Kovelman, on the medication cartridge 22 of Castellano et al. such that said information providing means is operatively coupled to injection mechanism 20 to improve the performance of the Castellano et al. apparatus.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano et al. in view of Cooper (US 5,836,904).

Castellano et al. do not disclose replaceable covers.

Art Unit: 3732

Cooper teaches replaceable covers for medical devices to provide comfort and enhanced appearance (col. 1, lines 58-65).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided replaceable covers as taught by Cooper on the device of the combination of Castellano et al. and Cooper for enhanced appearance.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR
January 4, 2004


KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700